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9 510(K) SUMMARY

9.1 General Information

Applicant: IBt, Inc.
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Contact Person IBt, Inc.: Ruth Feicht

Establishment Registration Number: 9035105 (IBt, Inc.)

Manufacturing Site: IBt s.a.
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Contact Person IBt s.a.: Sylviane Berger

Establishment Registration Number: 9031509 (IBt s.a.)

Classification Name:	Radionuclide Brachytherapy Source
Common/Usual Name:	Titanium sealed isotope; seed; interstitial implant
Proprietary Name:	InterStrand^{125} & InterStrand^{103} (InterStrand™ is a Trademark of IBt s.a.)
Model Number:	1251S and 103S
Classification:	Class II, same as the predicate device (see the Substantial Equivalence section below for predicate device information)
Special Controls:	InterStrand^{125} & InterStrand^{103} comply with the regulatory requirements for the Georgia Department of Natural Resources, Environmental Protection Division, Radioactive Materials Division for sealed brachytherapy implant sources.
Substantial Equivalence:	InterStrand™ sealed sources are substantially equivalent to the Medi-Physics I-125 Rapid Strand (Premarket Notification #K940632/S2), a Class II post-amendment device granted clearance to market on 2 September 1994.

9.2 The contents of this premarket notification summary will demonstrate the substantial equivalence of the subject device, InterStrand™, to the predicate device, the Amersham/ Medi-Physics I-125 Rapid Strand. The substantial equivalence will be based on the following important features of the device:

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9.2.1 Indications
9.2.2 Physical Size & Biocompatibility
9.2.3 Radioisotope
9.2.4 Radiation Dose

9.3 InterStrand™ Description
InterStrand™ consists of 10 sealed sources (either InterSource^{125} or InterSource^{103}) threaded onto an absorbable polyglyconate monofilament suture (Maxon synthetic suture by Sherwood, Davis and Geck) and spaced 1 cm center to center. The sealed sources are held in place by mechanically deforming the suture material, thus effectively increasing the diameter of the suture between seeds so that it exceeds the diameter of the opening within the seeds.

9.4 Table 6 compares the indications statement drafted for InterStrand™ with the predicate device's indications statement.

Table 6 Indications Statement Comparison Summary

InterStrand™	Predicate Device
InterStrand™ implants are indicated for interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor. InterStrand™ implants are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.	I-125 RAPID Strands™ are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They are to be used either as primary treatment (such as prostate cancer or unresectable tumors) or residual disease after excision of the primary tumor. I-125 RAPID Strand™ may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation or chemotherapy.

9.4.1 Based on the intent of the indications statement for the subject device, InterStrand™ is substantially equivalent to the predicate device with respect to its indications.

9.5 Table 7 and Table 8 compare the physical size, radiopaque marker, materials of construction, and the radioisotope for the subject device and the predicate device. Please note that in the case of both subject and predicate device the only materials in contact with the body are titanium and suture material both of which are biocompatible.

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Table 7 Feature Comparison

Feature Description	InterStrand™	*Predicate Device*
Outer Tube	*Medical grade titanium*	*Titanium*
Length	4.5 mm	4.5 mm
Outside Diameter	0.8 mm	0.8 mm
Isotope Carrier	*Medical grade titanium*	*Silver*
Shape	Hollow cylinder	Solid cylinder
Length	4.5 mm	3.0 mm
Diameter	0.6 mm	0.5 mm
Radiopaque Marker	*Platinum / Iridium Hollow cylinder*	*Silver Solid cylinder*
Inner Tube	*Medical grade titanium*	*Not Applicable*
Length	4.5 mm	Not Applicable
Outside Diameter	0.6 mm	Not Applicable
Encapsulation Method	*Laser Weld*	*Plasma Arc Weld*

Table 8 Radioisotope Comparison

Description	InterStrand™		Predicate Device
Radioisotope	Iodine-125	Palladium-103	Iodine-125
Half-life	59.4 days	16.99 days	59.4 days
Decay Mode	Electron capture to 35.5 keV level and ground state of Tellurium-125 with the emission of characteristic x-rays and a low energy (35.5 keV) gamma ray. The electrons and L-x-rays emitted from I-125 are absorbed by the titanium walls of the seed. All the remaining photons produced are in the range 27.2 to 35.5 keV	Electron capture to 39.8 keV and ground state of Rhodium-103 with the emission of characteristic x-rays and low yield gamma rays. The electrons and L-x-rays emitted from Pd-103 are absorbed by the titanium walls of the seed. Greater than 99% of the photons emitted from Pd-103 are within the range of 20.1 to 22.7 keV.	Electron capture to 35.5 keV level and ground state of Tellurium-125 with the emission of characteristic x-rays and a low energy (35.5 keV) gamma ray. The electrons and L-x-rays emitted from I-125 are absorbed by the titanium walls of the seed. All the remaining photons produced are in the range 27.2 to 35.5 keV
Principal Energy Levels (Yield/Branching Ratio)	27.2 keV (39.8%), 27.5 keV (74.3%), 31.0 keV (25.8%), 35.5 keV (6.68%)	20.1 keV (22.06%), 20.2 keV (41.93%), 22.7 keV (13.05%), 39.8 keV (0.0683%), 62.4 keV (0.001%), 295.0 keV(0.0028%), 357.4 keV(0.0221%), 497.1 keV (0.004%)	27.2 keV (39.8%), 27.5 keV (74.3%), 31.0 keV (25.8%), 35.5 keV (6.68%)
Residual Activity	< 1.1 µCi at 2 years	< 0.1 µCi at 2 years	< 1.3 µCi at 2 years

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9.5.1 Based on the outside dimensions of the subject device being the same as the predicate device, both devices having a radiopaque marker, the body tissue contacting materials being made of known biocompatible materials (titanium and suture material), and both devices using similar radionuclides, the subject device, InterStrand™ is substantially equivalent to the predicate device with respect to the physical size, biocompatibility, and radioisotope used.

9.6 Iodine-125 and palladium-103 seeds emit ionizing radiation to provide a therapeutic effect. The InterStrand™ seeds contain either I-125 or Pd-103 and these seeds are threaded onto a monofilament suture. The predicate device is only offered with I-125 seeds, and the seeds are placed inside the braided suture material. Because the suture material only absorbs a tiny fraction of the x-rays emitted from the sources, the method of associating the source with the suture has a negligible effect on the radiation dose distribution around the seed. While there is a measurable difference in dose distribution around I-125 and Pd-103 seeds, such seeds have previously been deemed substantially equivalent by the FDA. Therefore, the devices are substantially equivalent with respect to the distribution of the radiation dose. Figure 7 is a graphical presentation of the values (Meigooni, 2000 & Reniers, 2001) for radiation dose delivered by InterSource® and the reported dose (Shell, 1987) for the predicate device as a function of angle.

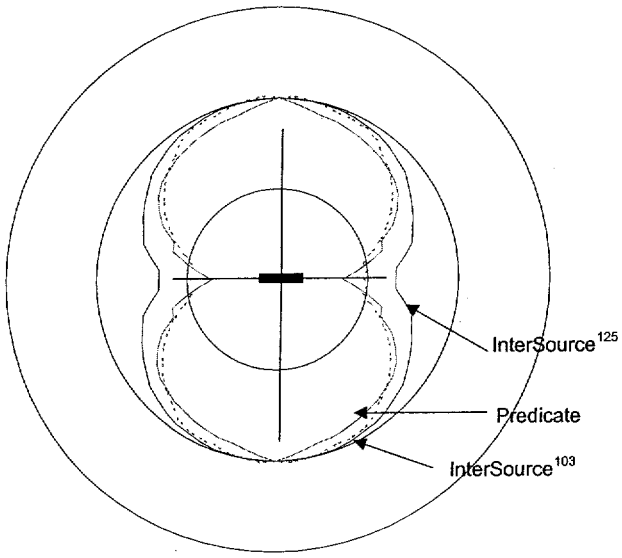

Figure 7 Distribution of Radiation Dose in Water at 2 cm

9.6.1 Based on InterStrand™ and the predicate device having a similar distribution of radiation dose, InterStrand™ is substantially equivalent to the predicate device with respect to radiation dose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Ms. Ruth Feicht
President
International Brachytherapy Inc.
6000 Live Oak Parkway
Suite 107
NORCROSS GEORGIA 30093

Re: K011155
InterStrand 125 & InterStrand 103
Model Numbers (1251S and 1031S)
Dated: April 13, 2001
Received: April 16, 2001
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Ms. Feicht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if Known): K011155

Device Name: InterStrand™

Indications For Use:

InterStrand™ implants are indicated for permanent interstitial implantation of select localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, lung, neck, pancreas, prostate, and unresectable tumors, or for residual disease after excision of the primary tumor. InterStrand™ implants are indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ________

David A. Segerson

(Division S...
Division of R...
and Radiolo...
510(k) Number K011155